Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s)

National Institutes of Health (NIH (http://www.nih.gov/))

U.S. Environmental Protection Agency (EPA (http://www.epa.gov/))

NOTE: This is a joint effort of NIH and EPA and includes requirements of both agencies. Applicants are encouraged to contact NIH and EPA with questions about requirements.

Components of Participating Organizations

National Institute of Environmental Health Sciences (NIEHS (http://www.niehs.nih.gov))
National Center for Environmental Research (NCER (http://www.epa.gov.ncer/))

Funding Opportunity Title

Children's Environmental Health and Disease Prevention Research Centers (P50)

Activity Code

P50 (http://grants.nih.gov/grants/funding/ac_search_results.htm?text_curr=p50&Search.x=0&Search.y=0&Search_Type=Activity) Specialized Center

Announcement Type

Reissue of RFA-ES-12-001 (http://grants.nih.gov/grants/guide/rfa-files/RFA-ES-12-001.html)

Related Notices

- October 24, 2014 - See Notice NOT-ES-15-003 (http://grants.nih.gov/grants/guide/notice-files/NOT-ES-15-003.html). Notice of Technical Assistance Webinar for RFA-ES-14-002 "Children's Environmental Health and Disease Prevention Research Centers (P50)"
- October 15, 2014 (http://grants.nih.gov/grants/guide/notice-files/NOT-ES-15-001.html) - See Notice NOT-ES-15-001 (http://grants.nih.gov/grants/guide/notice-files/NOT-ES-15-001.html). Notice of Technical Assistance Webinar for RFA-ES-14-002 "Children's Environmental Health and Disease Prevention Research Centers (P50)"
- NOT-ES-14-002 (http://grants.nih.gov/grants/guide/notice-files/NOT-ES-14-002.html)

Funding Opportunity Announcement (FOA) Number

RFA-ES-14-002

Companion Funding Opportunity

None

Number of Applications

Applicant organizations may submit more than one application provided that each application is scientifically distinct. See Section III. 3. Additional Information on Eligibility.

Catalog of Federal Domestic Assistance (CFDA) Number(s)

93.113, 66.509

Funding Opportunity Purpose

This Funding Opportunity Announcement (FOA) encourages grant applications to support a transdisciplinary program of basic and applied research to examine the effects of environmental factors on children's health and well-being. Research conducted through the Centers should include substantive areas of science in children's health while incorporating innovative technologies and approaches and links to the environment. This program encourages strong links between disciplines in the basic, applied, clinical and public health sciences to prevent disease and promote health of all children.

Key Dates

Posted Date

September 30, 2014

Open Date (Earliest Submission Date)

November 22, 2014

Letter of Intent Due Date(s)

November 22, 2014

Application Due Date(s)

December 22, 2014, by 5:00 PM local time of applicant organization. All types of non-AIDS applications allowed for this funding opportunity announcement are due on this date.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

AIDS Application Due Date(s)

Not Applicable

Scientific Merit Review

May 2015

Advisory Council Review

August 2015

Earliest Start Date

September 1, 2015

Expiration Date

December 23, 2014

Due Dates for E.O. 12372

Not Applicable

** ELECTRONIC APPLICATION SUBMISSION REQUIRED**

NIH's new Application Submission System & Interface for Submission Tracking (ASSIST) is available for the electronic preparation and submission of multi-project applications through Grants.gov to NIH. Applications to this FOA must be submitted electronically; paper applications will not be accepted. ASSIST replaces the Grants.gov downloadable forms currently used with most NIH opportunities and provides many features to enable electronic multi-project application submission and improve data quality, including: pre-population of organization and PD/PI data, pre-submission validation of many agency business rules and the generation of data summaries in the application image used for review.

Required Application Instructions

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), except where instructed to do otherwise (in this FOA or in a Notice from the *NIH Guide for Grants and Contracts (http://grants.nih.gov/grants/guide/)*) and where instructions in the Application Guide are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. Conformance to all requirements (both in the Application Guide and the FOA) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions. **Applications that do not comply with these instructions may be delayed or not accepted for review.**

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Part 2. Full Text of Announcement

Section I. Funding Opportunity Description

Background

NIEHS and EPA created the jointly funded Centers for Children's Environmental Health and Disease Prevention Research Program (Children's Centers) in 1998. The guiding principle for this program is to safeguard and promote the healthy growth and development of children, protect them from potential environmental threats and improve the environments where they live, learn and play using a sustainable and holistic approach.

The program includes community-based projects, applied and basic science research approaches, as well as community outreach and translation components to facilitate multi-directional communication with appropriate groups. EPA/NIEHS Children's Centers use multidisciplinary approaches to look at the consequences of exposures to environmental chemicals on the health of children and adolescents. By combining research and community-engagement, the Children's Centers provide the foundation for a broad base of research on children’s environmental health. They have developed a national network of researchers, health care professionals, advocacy and parents groups to address a range of harmful environmental exposures and other factors that may affect children’s health outcomes.

A holistic approach includes factors that may impact a child’s health and well-being including a child’s developmental stage, physiology, and activities and behaviors, and environmental agents, chemical and non-chemical stressors, economic, and societal (both family and community) factors as well.

Purpose

NIEHS and EPA will continue to support and facilitate integrated fundamental, clinical, laboratory, and public health science to: (1) identify the harmful influences of environmental exposures and changing environments as well as the protective and nurturing impact of healthy environments on normal physiological function of organs and systems of the fetus/child during gestation/childhood/adolescence; (2) determine the mechanisms of vulnerability to environmental stressors of the fetus and young child at all stages of early development; and (3) consider children’s health from a holistic perspective where the impact of complex environmental exposures may be exacerbated by non-chemical stressors encountered in community settings.

Chemical stressors may be considered as single chemicals, or as mixtures and aggregates as may be found in consumer products used by children and environments and microenvironments frequented by children. Non-chemical stressors include mediating and modifying factors such as economic deprivation, discrimination, poverty, lack of health care, fear of crime, diet and nutrition, physical activity, psychosocial factors, and the design of the built environment (e.g., settings: home, school, play areas) from birth through young adulthood. Non-chemical stressors, social and cultural factors, and settings cannot be considered alone, but they may be included as modifier variables to the primary environmental stressor(s).

NIEHS and the EPA recognize that healthy children are the foundation of sustainable communities. Therefore, in addition to considering the health impacts of children’s environments, the Children’s Centers Program is evolving to incorporate principles of sustainability as articulated in the recent National Academy of Sciences report on Sustainability (available at: http://www.nap.edu/catalog.php?record_id=13152 (http://www.nap.edu/catalog.php?record_id=13152)).

Research Objectives, Expected Outputs and Outcomes

NIEHS and EPA have developed a joint program with multiple opportunities to enhance research focused on advancing scientific understanding of key determinants of children’s environmental health to meet each Agency’s

mission by filling identified research gaps to promote healthy environments for children. This Funding Opportunity Announcement (FOA) is designed to encourage applications from transdisciplinary research teams proposing an integrated multi-project approach and a well-developed research program of innovative research. NIEHS and EPA consider community engagement to be a major goal of the program; as such, applications must include a Community Outreach and Translation Core.

The objectives are to (1) leverage and build upon the research findings and resources from epidemiological and clinical studies of pregnant women or parents and children; (2) enhance the application of novel findings and approaches in areas of basic or mechanistic research e.g., imaging, epigenetics, metabolomics, and comparative biology to developmental human studies; (3) develop, validate, discover and apply new or improved lifestage-specific biomarkers of exposure and early effect to elucidate complex relationships between environmental factors and health outcomes across the lifestages, environmental measurements (e.g., personal, indoors, outdoors, and understudied areas/regions where data on children's environments is limited), and exposure factors and models to best characterize exposure, cumulative impacts, effects modifiers and associated health effects, and to predict longer-term clinical/adverse consequences; (4) introduce new investigators to state-of-the-art tool and methodologies to address emerging issues in children's environmental health; and (5) ensure active participation of identified stakeholders and the broader community in the research process, and translation and application of research findings for disease prevention and health promotion.

Outputs (results) expected from the research funded under this FOA may include:

- Original peer-reviewed articles and synthesis reports, some of which could inform children's health decision makers (parents, medical care providers, local governance, and policy makers) such as advances in the understanding of environmental factors associated with developmental endpoints.
- Analysis of complex biological, environmental and socio-economic datasets to provide insight into potential interaction of these domains and their combined influence on disease occurrence or prevention.
- Advanced methods and models to measure and characterize environmental and exposure factors, lifestage-specific approaches for estimating children's health risks, evaluating complex exposures, advanced statistical models for incorporating non-chemical stressors and lifestage-specific considerations such as factors related to behavior; new or improved biomarkers of exposure, susceptibility, and/or effects for predicting and identifying children's health risks and evaluating prevention strategies. This is especially important for the youngest lifestages up to <6 years old and understudied lifestages such as puberty.
- Novel, efficient, low subject-burden tools and methods to characterize complex exposures and/or risk from multiple stressors (e.g., environmental, socio-economic), sources and routes, and/or better predict and measure early endpoints predictive of health outcomes to support health protective public policy and community-based decisions.
- Developed and evaluated mitigation strategies that quantitatively reduce risks and promote children's health (e.g., prevention and/or intervention), especially in research/clinical areas where impact of the specific environmental factors on children's health has been observed.
- Resources for use by communities and/or healthcare providers to inform and guide stakeholders including parents regarding both the extent of environmental influences on child well-being and how to eliminate or reduce harmful environmental exposures (e.g., reports, factsheets, best practices, software).

Expected outcomes (potential benefits) of the proposed research include:

- The use of (1) tools and methods for more rigorous analyses of children's health risks and (2) basic science and/or population-based research findings to inform decision-making to reduce or eliminate potentially harmful environmental exposures to children's health in community settings.

- An increased number of investigators with expertise in cross-disciplinary fields in children's environmental health based on the latest scientific discoveries.
- Active engagement of a community and other stakeholders in basic and/or population-based research which may result in an increase in the number of community and other stakeholders prepared to engage in, support and participate in population-based research.
- Translation and sharing of research findings and models which could inform health-protective and health promoting decision making by health care professionals and providers, state and local governments, public health policy makers and the public.

Research Approaches

The types of research approaches that are encouraged under this FOA include but are not limited to the following:

- Identifying and testing new research hypotheses probing environmental linkages to childhood diseases and disorders using existing human studies, registries, datasets, environmental samples (both stored and newly collected) and biospecimens.
- Assessing the cumulative risk of multiple environmental exposures in multiple media (e.g., air, water, land) and stressors over time on children's health and/or improving understanding of the complex interplay between factors such as longitudinal aggregate and cumulative exposures from multiple exposure routes, at various dose levels, genetics/gene variants and epigenetics for complex disease risk at different lifestage.
- Exposure sciences to develop evidence-based strategies for eliminating and reducing harmful environmental exposures to children, including low subject-burden exposure assessment approaches and innovative tools.
- Integrating multiple study populations or consortia to pool common data elements or to conduct comparable analyses to improve the ability to assess the harmful and potentially cumulative effect(s) of multiple exposures/media/stressors.
- Approaches for evaluating complex real-world exposures to large sets of environmental agents in the context of important chemical and non-chemical stressors.
- Interdisciplinary approaches to studying children's environmental health, including effect modification by non-chemical factors such as socioeconomic status, race/ethnicity, stress, nutrition or protective behaviors that may modify or influence the relationship between exposure and health relationship.
- Research that could lead to better understanding of environmental health issues of children living in rural communities, and understudied regions where data on children's environmental health is limited.
- Mechanistic laboratory studies utilizing in vitro, in vivo, and/or in silico models of molecular, cellular, tissue and organism responses to developmental perturbation by environmental agents, as one project component, if justified in order to test hypotheses about the environment-disease linkage under study in the overall project.
- Translation and application of animal models to human health, epidemiological and/or clinical investigation.
- Systems approaches to obtain, integrate and analyze complex environmental and biological, socio-economic, and biological data arising from multiple sources using interdisciplinary tools such as Geographic Information Systems (GIS).

- Enhanced involvement of impacted communities in the research process. Community-engaged Research (CEnR) methods/approaches are encouraged, which include Community-Based Participatory Research (CBPR). CBPR is an advanced level of CEnR that is defined as a process of scientific inquiry such that community members, persons affected by the health condition, disability or issue under study, or other key stakeholders in the community have the opportunity to be full participants with substantial involvement in all phases of the work (from conception to design, implementation, analysis, interpretation, conclusions, and communication of results).
- Development and evaluation of targeted prevention and intervention efforts, including “natural experiments”, to protect children’s health.

Research Topics of Interest

Research Topics of interest on which applications may be focused under this FOA include, but are not limited to, those listed below. In all cases, applicants should show how the application will significantly advance the field rather than confirm or refine earlier findings or models.

- Characterization of life stage specific environmental exposures (chemical and non-chemical), and related outcomes:
- in settings of greatest importance for children’s exposures (such as homes, child care centers, schools, and playgrounds) and development of strategies to reduce or prevent adverse exposures in those settings.
- by using emerging technologies or approaches such as development of appropriate biomarkers, to improve lifestage-specific exposure and dose estimates; and/or examine the influence of early lifestage environmental exposures on development of disease in childhood.
- by evaluating lifestage-specific exposure pathways that may influence vulnerability to multiple stressors and/or contribute to disease onset/disease course in children.
- Characterization of effects (including mechanisms) of in utero and/or perinatal and/or childhood exposures to chemical and non-chemical environmental stressors on biological changes associated with adverse childhood or later health outcomes including:
- diseases or disorders where linkage to environmental factor(s) is suspected but not well established (e.g., adverse birth outcomes such as prematurity, birth defects, autoimmune disorders, neurodevelopmental disorders, childhood cancers, childhood obesity, metabolic disorders, neuropsychiatric and neurological disorders) in population groups not well represented in the published scientific literature (such as Asian and Pacific Islander and Native American children, and children living in rural areas.)
- identification of developmental stages that might be particularly susceptible to certain environmental exposures/health concerns.
- exploration of mechanisms through which chemical and non-chemical stressors impact children's health, including gene environment interactions and epigenetic changes.
- Application of a systems-based approach to reduce children’s health risks and adverse health outcomes from environmental hazards through improved understanding of cumulative risk:
- resulting from interactions between co-exposures to environmental chemicals and psychosocial, or socioeconomic factors and other environmental factors that may act on different pathways and/or increase the vulnerability or resilience of the fetus, children and/or adolescents.
- to evaluate the effectiveness and/or benefits of strategies such as exposure avoidance and disease management.

Required Elements

Each Children Center must propose an overall scientific research theme and plan related to the role of the environment in the etiology and prevention of children's adverse health outcomes that are responsive to the objectives of the NIEHS and EPA Children's Centers Program and responsive to the mission of each Agency.

Applicants must study one or more environmental agent(s)/chemical(s)/stressor(s) to which there is human exposure and or the potential for exposure. This could include any endocrine disrupting chemical(s), neurotoxicants(s), synthetic/organic pollutants, organic solvents, flame retardants, particulate matter (PM) or other air pollutants, pesticides, perfluorinated compounds, plasticizers, metals and/or emerging contaminants of concern (such as nanomaterials). The inclusion of social determinants of health (SDH) and/or non-chemical stressors, as modifying factor(s), is encouraged in at least one of the projects and where possible, in other components of the Center application. Non-chemical stressors (e.g., nutrition, social, economic, stress, socioeconomic status, race/ethnicity, and cultural factors) cannot be considered alone, but applicants are encouraged to include them as secondary or modifying variables to the primary environmental stressor(s).

The application must contain 3 unique but integrated research projects related to the Center's theme. The application must also address 3 essential elements:

- Community Engagement: The CEHC program views Community Engagement as an effective way to inform and advance science for public health protection. Community Engagement connects the Center's science with issues that are identified as locally relevant by communities or stakeholders and may often complement the research strengths and problem-solving goal of the Center. All applicants are required to include Community Engagement as part of their Center to support the needs of the community with regard to the science emanating from the Center. This may include a Community-Based Participatory Research (CBPR) project demonstrating the collaborative process of research involving both researchers and community representatives and/or implementation of a community advisory board.
- Health Specialist: Center staff must include at least one health specialist, who is an active researcher in a field directly relevant to the Center's theme (e.g., pediatric health specialists, obstetrician, psychologist, allergist, and or birth defects expert).
- Career development: The CEHC program views fostering of the next generation of scientists in children's environmental health to be of essential importance. Therefore, Center Program Director's are encouraged to consider inclusion of an early stage investigator. One individual should be designated for career development in the application.

Each Children Center must also include the following required two Cores:

- Administrative Core to provide oversight, coordination and integration of Center activities.
- Community Outreach and Translation Core (COTC) to help develop and sustain community outreach, engagement, and translation activities at the Center. The COTC promotes multi-directional communication among the Center and its stated target audiences on issues of prevention, environmental health literacy, and environmental public health.

EPA Requirements

The specific Strategic Goal and Objective from the EPA's Strategic Plan that relate to this FOA are: Goal 3: Cleaning Up Communities and Advancing Sustainable Development, Objective 3.1: Promote Sustainable and Livable Communities. The EPA's FY 2014-2018 Strategic Plan can be found at http://www2.epa.gov/planandbudget/strategicplan (http://www2.epa.gov/planandbudget/strategicplan). The NIEHS strategic plan can be found at http://www.niehs.nih.gov/about/strategicplan/ (http://www.niehs.nih.gov/about/strategicplan/).

Recipients of NIH and EPA grant funds must comply with all applicable Federal statutes (such as those included in appropriations acts) regulations, and policies (see Section VIII).

To be eligible for EPA funding consideration, a project's focus must to consist of activities within the statutory terms of EPA's financial assistance authorities; specifically, the statute(s) listed below (see Section VIII). Generally, a project must address the causes, effects, extent, prevention, reduction, and elimination of air pollution, water pollution, solid/hazardous waste pollution, toxic substances control, or pesticide control depending on which statute(s) is listed above. These activities should relate to the gathering or transferring of information or advancing the state of knowledge. Applications should emphasize this "learning" concept, as opposed to "fixing" an environmental problem via a well-established method. Applications relating to other topics which are sometimes included within the term "environment" such as recreation, conservation, restoration, protection of wildlife habitats, etc., must describe the relationship of these topics to the statutorily required purpose of pollution prevention and/or control.

EPA has specific application guidance for research that involves human subjects. Please see the last paragraph of this section for further information pertaining to the need of this guidance, and Section IV, "EPA Human Subjects Research Statement (HSRS)" of this FOA for specific instructions.

Agency policy and ethical considerations prevent EPA technical staff and managers from providing applicants with information that may create an unfair competitive advantage. Consequently, EPA employees will not review, comment, advise, and/or provide technical assistance to applicants preparing applications in response to EPA FOAs. EPA employees cannot endorse any particular application.

These awards may involve the collection of "Geospatial Information," which includes information that identifies the geographic location and characteristics of natural or constructed features or boundaries on the Earth or applications, tools, and hardware associated with the generation, maintenance, or distribution of such information. This information may be derived from, among other things, a Geographic Positioning System (GPS), remote sensing, mapping, charting, and surveying technologies, or statistical data.

This FOA provides the opportunity for the submission of applications for projects that may involve human subjects research. Human subjects research supported by the EPA is governed by EPA Regulation 40 CFR Part 26 (Protection of Human Subjects). This includes the Common Rule at subpart A and prohibitions and additional protections for pregnant women and fetuses, nursing women, and children at subparts B, C, and D. Research meeting the regulatory definition of intentional exposure research found in subpart B is prohibited by that subpart in pregnant women, nursing women, and children. Research meeting the regulatory definition of observational research found in subparts C and D is subject to the additional protections found in those subparts for pregnant women and fetuses (subpart C) and children (subpart D). All applications must include a Human Subjects Research Statement (HSRS, as described in Section IV), and if the project involves human subjects research, it will be subject to an additional level of review prior to funding decisions being made as described in Section V of this FOA.

Guidance and training for investigators conducting EPA-funded research involving human subjects may be obtained here:

http://www.epa.gov/osainter/phre/support.htm (http://www.epa.gov/osainter/phre/support.htm)

http://www.epa.gov/osa/pdfs/phre/phre_course/index.htm (http://www.epa.gov/osa/pdfs/phre/phre_course/index.htm)

For human subjects research applications, there are many scientific and ethical considerations that must be addressed by the study sponsor and research team, including, but not limited to, those related to recruitment, retention, participant compensation, third-party issues, researcher-participant interactions, researcher-community interactions, communications, interventions, and education. All such research must comply with the requirements of the Common Rule (40 CFR Part 26), and any human observational exposure studies must also adhere to the principles set forth in the Scientific and Ethical Approaches for Observational Exposure Studies (SEAOES) (EPA/600/R-08/062) (http://www.epa.gov/nerl/sots/SEAOES_doc20080707.pdf (http://www.epa.gov

/nerl/sots/SEAOES_doc20080707.pdf)) document. SEAOES, which was published by researchers in EPA and which discusses the principles for the ethical conduct of human research studies, serves as a resource for applicants interested in applying under this FOA. References to "SEAOES Principles" in this FOA refer, in general, to the issues of interest in conducting human subjects research studies that maintain the highest scientific and ethical standards and safety during the conduct of these studies. All applications must include a Human Subjects Research Statement (HSRS; described in Section IV) and if the project involves human subjects research, it will be subject to an additional level of review prior to funding decisions being made as described in Section V of this FOA.

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New
Renewal

The OER Glossary (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11116) and the SF424 (R&R) Application Guide provide details on these application types.

Funds Available and Anticipated Number of Awards

NIEHS and EPA intend to fund an estimate of 5 awards, corresponding to $7.0 million total cost per year, which includes direct and Facilities and Administrative (F&A) costs, for 4 years beginning in fiscal year 2015. Future year amounts will depend on annual appropriations.

EPA and NIEHS plan to concurrently fund Centers with funding shared by EPA and NIEHS and managed by both EPA and NIEHS. If a Center is concurrently funded, the Center will be supported by two awards: one which provides the EPA portion of the budget, and a companion award which provides the NIEHS portion of the budget. There may be an opportunity for a Center to be funded by only one agency related to mission priorities or program needs, in which case the Center will receive one award by the funding agency.

In appropriate circumstances, EPA reserves the right to partially fund applications by funding discrete portions or phases of proposed projects. If EPA decides to partially fund an application, it will do so in a manner that does not prejudice any applicants or affect the basis upon which the application, or portion thereof, was evaluated and selected for award, and therefore maintains the integrity of the competition and selection process.

Both NIEHS and EPA reserve the right to reject all applications and make no awards, or make fewer awards than anticipated, or to make additional awards consistent with the policies of the Agencies, if additional funding becomes available after the original selections are made. Any additional selections for awards will be made no later than six months after the original selection decisions.

The number of awards is contingent upon NIH and EPA appropriations and the submission of a sufficient number of meritorious applications.

Award Budget

For each Center, application budgets are limited to $1.5 million per year total costs for up to 4 years for renewal applications and $1.25 million per year total costs for up to 4 years for new applications.

Award Project Period

The total project period may not exceed 4 years.

NIH grants policies as described in the *NIH Grants Policy Statement (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120)* will apply to the applications submitted and awards made in response to this FOA.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)
- U.S. Territory or Possession

Other

- Independent School Districts

- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Note: Nonprofit organizations described in Section 501(c) (4) of the Internal Revenue Code that lobby are not eligible to apply for EPA funding. Profit-making firms are also not eligible to receive grants from EPA under this program.

National laboratories funded by Federal Agencies (Federally-Funded Research and Development Centers, "FFRDCs") may not apply. FFRDC employees may cooperate or collaborate with eligible applicants within the limits imposed by applicable legislation and regulations. They may participate in planning, conducting, and analyzing the research directed by the applicant, but may not direct projects on behalf of the applicant organization. The institution, organization, or governance receiving the award may provide funds through its assistance agreement from the EPA to an FFRDC for research personnel, supplies, equipment, and other expenses directly related to the research. However, salaries for permanent FFRDC employees may not be provided through this mechanism.

Federal Agencies may not apply.

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.
Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as defined in the *NIH Grants Policy Statement* (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11118), **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-035.html) states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- Dun and Bradstreet Universal Numbering System (DUNS) (http://fedgov.dnb.com/webform) - All registrations require that applicants be issued a DUNS number. After obtaining a DUNS number, applicants can begin both SAM and eRA Commons registrations. The same DUNS number must be used for all registrations, as well as on the grant application.
- System for Award Management (SAM) (https://www.sam.gov/portal/public/SAM/) (formerly CCR) – Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
- eRA Commons - Applicants must have an active DUNS number and SAM registration in order to complete the eRA Commons registration. Organizations can register with the eRA Commons as they are working through their SAM or Grants.gov registration. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in

order to submit an application.

- Grants.gov (http://www.grants.gov/applicants/organization_registration.jsp) – Applicants must have an active DUNS number and SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons.If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with his/her organization to develop an application for support. Individuals from underrepresented racial and ethnic groups as well as individuals with disabilities are always encouraged to apply for NIH support.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide

Federal employees are not eligible to serve in a principal leadership role on an assistance agreement, and may not receive salaries or augment their Agency's appropriations in other ways through awards made under this program

2. Cost Sharing

This FOA does not require cost sharing as defined in the *NIH Grants Policy Statement*. (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11126)

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see NOT-OD-11-101 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-101.html)).

In addition, the NIH will not accept a resubmission (A1) application that is submitted later than 37 months after submission of the new (A0) application that it follows. The NIH will accept submission:

- To an RFA of an application that was submitted previously as an investigator-initiated application but not paid;
- Of an investigator-initiated application that was originally submitted to an RFA but not paid; or

- Of an application with a changed grant activity code.

Section IV. Application and Submission Information

1. Requesting an Application Package

Applicants can access the SF424 (R&R) application package associated with this funding opportunity using the "Apply for Grant Electronically" button in this FOA or following the directions provided at Grants.gov (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11127).

Most applicants will use NIH's ASSIST system to prepare and submit applications through Grants.gov to NIH. Applications prepared and submitted using applicant systems capable of submitting electronic multi-project applications to Grants.gov will also be accepted.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the SF424 (R&R) Application Guide (http://grants.nih.gov/grants/guide/url_redirect.htm?id=12000), including Supplemental Grant Application Instructions (https://grants.nih.gov/grants/funding/424/SupplementalInstructions.pdf) except where instructed in this funding opportunity announcement to do otherwise and where instructions in the Application Guide are directly related to the Grants.gov downloadable forms currently used with most NIH opportunities. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

For information on Application Submission and Receipt, visit Frequently Asked Questions – Application Guide, Electronic Submission of Grant Applications (http://grants.nih.gov/grants/guide/url_redirect.htm?id=41137).

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Linda Bass, Ph.D.
National Institute of Environmental Health Sciences
Telephone: 919-541-1307
Email: bass@niehs.nih.gov

Page Limitations

Component Types Available in ASSIST	Research Strategy/Program Plan Page Limits
Overall	12

Component Types Available in ASSIST	Research Strategy/Program Plan Page Limits
Admin Core	12
COTC	6
FSC	6
Project (use for Research Project)	12

Additional page limits described in the SF424 Application Guide and the Table of Page Limits (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11133) must be followed.

Instructions for the Submission of Multi-Component Applications

The following section supplements the instructions found in the SF424 (R&R) Application Guide, and should be used for preparing a multi-component application.

The application should consist of the following components:

Overall: Required

- Administrative Core: Required
- Community Outreach and Translation Core (COTC): Required
- Facility/Service Core (FSC): Optional

Research Projects: 3 Required

Overall Component

When preparing your application in ASSIST, use Component Type 'Overall'.

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Overall)

Complete entire form.

PHS 398 Cover Page Supplement (Overall)

Note: Human Embryonic Stem Cell lines from other components should be repeated in cell line table in Overall component.

Research & Related Other Project Information (Overall)

Follow standard instructions.

Project/Performance Site Location(s) (Overall)

Enter primary site only.

A summary of Project/Performance Sites in the Overall section of the assembled application image in eRA Commons compiled from data collected in the other components will be generated upon submission.

Research & Related Senior/Key Person Profile (Overall)

Include only the Project Director/Principal Investigator (PD/PI) and any multi-PDs/PIs (if applicable to this FOA) for the entire application.

A summary of Senior/Key Persons followed by their Biographical Sketches in the Overall section of the assembled application image in eRA Commons will be generated upon submission.

Budget (Overall)

The only budget information included in the Overall component is the Estimated Project Funding section of the SF424 (R&R) Cover.

A budget summary in the Overall section of the assembled application image in eRA Commons compiled from detailed budget data collected in the other components will be generated upon submission.

PHS 398 Research Plan (Overall)

Specific Aims: Specific aims should be built around serving the goals of the program project.

Research Strategy:

Applicants must propose an overall research theme and plan that are responsive to the objectives of the NIEHS and EPA Children's Centers Program. The central scientific theme should be related to the role of the environment (defined broadly) in the etiology and prevention of adverse health outcomes in children.

The program overview section describes the significance, innovation and approach of the overall application and should highlight the program's conceptual unity by describing the scientific problems to be addressed and laying out a broad research strategy to address them. A Center should be viewed as a group of interrelated research projects, each of which is not only individually meritorious scientifically but also complementary to and interrelated with the other projects in the research program that contribute to the integrating theme. The theme of a proposed Center should be established in the first few sentences of the general introduction. It should include a description of the major research objectives and strategic plan. Explain how the proposed projects and shared resource cores (if proposed) will be coordinated and work together to address the overall goals and aims of the program more effectively than if the projects were conducted independently.

Letters of Support: Letters of support for the P50 Center overall should be included with the Overall Component. For program activities to be conducted off site, i.e., at an institution other than the applicant institution, a letter of assurance or comparable documentation, signed by the collaborator as well as the off-site institutional official, must be submitted with the application.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide, with the following modification:

All applications, regardless of the amount of direct costs requested for any one year, should address a Data Sharing Plan.

Each Children Center application is expected to include a data sharing plan to facilitate data sharing with other Centers, federal researchers, the public and key stake holders. Applicants are expected to provide a plan to make all data resulting from an agreement under this FOA available in a format and with documentation/metadata such that they may be used by others in the scientific community. This includes data first produced under the award, i.e., from observations, analyses, or model development collected or used under the agreement. Applicants who plan to develop or enhance databases containing proprietary or restricted information are expected to provide, within the two pages, a strategy to make the data widely available, while protecting privacy or property rights.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Administrative Core

When preparing your application in ASSIST, use Component Type ‘Admin Core.’

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Administrative Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant’s Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Administrative Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Administrative Core)

Human Subjects: Answer only the ‘Are Human Subjects Involved?’ and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the ‘Are Vertebrate Animals Used?’ question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components

Project /Performance Site Location(s) (Administrative Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Administrative Core

In the Project Director/Principal Investigator section of the form, use Project Role of ‘Other’ with Category of ‘Core Lead’ and provide a valid eRA Commons ID in the Credential field.

- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.
- Describe the Health Specialist and their expertise and role in the overall integration of the proposed projects and the support of the overall translation central theme of the Center . This individual must be an active researcher who is qualified to assist with coordination and integration of the scientific projects and who will help ensure that the science under investigation will translate to clinical practice and/or have a positive impact on public health. This person may come from any discipline that traditionally has direct

contact with young children or mothers in a treatment-based environment; however, the expertise should be suited to the Center's scientific theme. This individual should be distinct from the Center Program Director. The Health Specialist may also serve as a project leader/co-leader/collaborator.

- Individuals in senior leadership positions should provide intellectual, administrative, and scientific leadership for the Center and are critical to its overall effectiveness and evolution. These individuals should be in place and committed to a defined percent effort.

Budget (Administrative Core)

Budget forms appropriate for the specific component will be included in the application package.

Each Center must budget $5,000 per year to support the annual CEHC Meetings in venues to be determined in collaboration with the Center Investigators and NIEHS and EPA program staff. Travel costs should also budget for Children's Center members to travel to the annual 1-2 day meeting at a minimum for the Director, Project Investigators and COTC Director. Each CEHC should expect to host such a meeting once within the project period and may want to set funds aside for the event. Please consult with program staff for details.

Indicate who will be responsible for achieving project objectives and communicating with NIEHS and EPA.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Administrative Core)

Specific Aims: State the aims for the Administrative Core.

Research Strategy: Administrative Core is to provide oversight, coordination, and integration of Center activities. Unless otherwise performed by the COTC, the Administrative Core should coordinate community engagement and facilitate meaningful exchange between Center investigators, the community, and stakeholders.

An External Advisory Committee (EAC) to the Center Director should be established and managed as part of the Administrative Core. The function of the EAC is to assist in evaluating the merit, value and ongoing progress of each research project and the relevance and importance of individual organizational elements to accomplish the overall goals of the Center. This group should consist of three to five members having expertise appropriate for the Center's research focus, plus one representative from a community group. Representation from a state or local health department is also encouraged. At least two-thirds (67 percent) of the Committee members should be from outside the grantee institution. The EAC should meet at least twice over the life of the grant and NIEHS and EPA staff should be notified of the meeting and invited to attend. The written recommendations of the EAC should be provided to the PD/PI as part of the annual progress report. Names of potential EAC members should not be solicited or submitted in the application. Only submit a description of proposed protocols and planned committee by representation and area of expertise. If awarded, the PD/PI will be asked to provide an identifiable list of membership to the EAC for review by the funding agencies.

It is expected that organization of the Administrative Core will provide a supportive structure sufficient to ensure accomplishment of the following:

- Coordination and integration of CEHC components and activities.
- Assessment of productivity, effectiveness, and appropriateness of CEHC activities and determination of CEHC membership assessment of scientific opportunities and areas for collaboration among all CEHC members.
- Organization of CEHC activities, , invitation of consultants, meetings, and focus groups.

- Organization and management of the External Advisory Committee.
- Record keeping of meeting minutes and measures of success including: publications, supplemental research projects, mentoring of new scientists, new grant applications and awards generated from Center results or scientific inquiry.
- Interactions and collaborations with other CEHCs, NIEHS, EPA and other appropriate individuals, groups, or organizations that promote and support children's environmental health.

A successful CEHC application will include a well-integrated project plan. Within the Administrative Core, the specific administrative and organizational structure that is needed to support the research and the synergies enabled by the Center needs to be clearly articulated. CEHC projects will be multidisciplinary and interdisciplinary and will draw from a variety of resources. Thus, a well thought out and carefully described organizational structure is encouraged, the oversight of fiscal and resource management including the approach, procedures, and controls for ensuring that awarded grant funds will be expended in a timely and efficient manner.

A narrative description should be provided that includes the planning and coordination of research activities; the integration of cross-disciplinary research; the tracking of progress towards Center outputs and outcomes.

Please provide details about how project objectives will be successfully achieved within the project period; and the maintenance of ongoing communication with NIEHS and EPA. Indicate who will be responsible for each of these activities. Describe the involvement of advisory groups and consultants.

Describe how the Administrative Core will coordinate the research activities with existing resources, activities or programs at the institution. No specific funds should be used to develop new training programs or to directly support existing training programs; however, a listing of available resources to recruit new investigators should be provided. A plan for tracking the impact of CEHC on investigator development should be described.

Career Development. In order to foster the next generation of creative new scientists in children's environmental health, Center Program Directors are required to support the research career development of new, junior faculty-level investigators within the structure of the Children's Center. We encourage applicants to consider inclusion of an early stage investigator. One individual should be designated for Career Development in the application. This person will be expected to devote a minimum of 3 person-months of the award and have a long-term commitment to research in the environmental health sciences. The Career Development Investigator (CDI) may hold either a health professional doctorate (M.D., D.O, Pharm. D., doctoral degree in nursing, or other equivalent degree) or a research doctoral degree (Ph.D., or equivalent); should have fewer than eight years of postdoctoral experience (excluding clinical training years) at the time the application is submitted; and should have demonstrated outstanding abilities in basic, clinical or population based research. Designated CDIs must meet the NIH definition of New Investigator, (http://grants.nih.gov/grants/new_investigators/index.htm#definition (http://grants.nih.gov/grants/new_investigators/index.htm#definition)). The Program Director must develop and describe a career development plan proposed to be undertaken by the CDI. The Career Development plan should be included as part of the Administrative Core If the candidate is unknown at time of submission, a general plan to recruit the CDI is required.

Describe how the Administrative Core will coordinate meetings of CEHC investigators with investigators from other CEHCs including active participation in planning the Children's Centers meeting.

Describe the engagement of at least one Health Specialist directly relevant to the Center's theme (e.g., pediatric health specialist, clinical expert in the disease area under investigation.)

Letters of Support: Include letters of support for any collaborative/cooperative arrangements, subcontracts, or consultants. The Program Director must provide a letter of recommendation for the designated Career Development Investigator, if one is identified at the time of application. A letter from the CDI candidate outlining

his/her career goals should also be included in the application.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide, with the following modification:

Each Children Center application is expected to include a data sharing plan to facilitate data sharing with other Centers, federal researchers, the public and key stake holders. Applicants are expected to provide a plan to make all data resulting from an agreement under this FOA available in a format and with documentation/metadata such that they may be used by others in the scientific community. This includes data first produced under the award, i.e., from observations, analyses, or model development collected or used under the agreement. Applicants who plan to develop or enhance databases containing proprietary or restricted information are expected to provide, within the two pages, a strategy to make the data widely available, while protecting privacy or property rights.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report (Administrative Core)

Not Applicable

PHS 398 Cumulative Inclusion Enrollment Report (Administrative Core)

Not Applicable

Community Outreach and Translation Core

When preparing your application in ASSIST, use Component Type ‘COTC.’

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Community Outreach and Translation Core)

Complete only the following fields:

- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant’s Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Community Outreach and Translation Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Community Outreach and Translation Core)

Human Subjects: Answer only the ‘Are Human Subjects Involved?’ and 'Is the Project Exempt from Federal regulations?’ questions.

Vertebrate Animals: Answer only the ‘Are Vertebrate Animals Used?’ question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating

it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components

Project /Performance Site Location(s) (Community Outreach and Translation Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Community Outreach and Translation Core)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.
- The COTC must include personnel from one or more of the following areas: health educators, nurses, members of community or faith-based organizations, members of organizations which advocate for research and services pertaining to children's health, members of professional societies of health care professionals, and state and local health departments or medical service organizations.

Budget (Community Outreach and Translation Core)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Community Outreach and Translation Core)

Specific Aims: Specific aims of the COTC should be built around serving the goals of the program project.

Research Strategy: The applicant should describe how this Core will help develop and sustain community outreach, engagement, and translation activities at the Center. The Children's Centers are required to translate and apply their research findings into information for the affected communities, general public, policy-makers and health care professionals with the ultimate goal of protecting children. The COTC promotes multi-directional communication among the Center and its stated target audiences on issues of prevention, environmental health literacy, and environmental public health. To this end, the COTC should develop, demonstrate and evaluate strategies to translate and apply the scientific findings of the Center into information for the public, policymakers, and clinical professionals to use to protect the health of children. In addition, the COTC should describe a variety of mechanisms to be used to facilitate and enable the community/stakeholders to communicate environmental health concerns to Center members. These may include, for example, the creation of translational materials for health professions, development of novel strategies for dissemination of research findings to the broad audience of stakeholders, and assessment of community understanding of research results and plans for action.

As part of the Partnerships for Environmental Health (PEPH) program, NIEHS has created a database management system to archive, share, and disseminate outreach materials developed within an environmental research portfolio. COTCs should develop a plan on how they will manage their developed materials and utilize the NIEHS maintained repository at http://www.niehs.nih/research/supported/dert/programs/peph/materials/index.cfm (http://www.niehs.nih/research/supported/dert/programs/peph/materials/index.cfm). COTCs are encouraged to use this repository as a tool for learning from, and interacting with, other Centers and grantees with a shared mission of translating EHS research, as well as for the management of Center materials development with the intention for broader outreach to the environmental health research community, stake holders and public. NIEHS will facilitate gaining access to this database and NIEHS will be responsible to manage and maintain the repository and to facilitate outreach efforts.

Describe a plan to collect, integrate and disseminate research findings and Centers activities for the public, policy makers, and clinical professionals to use to protect the health of children.

Describe the membership of the COTC and types of expertise to be recruited to enhance effective communication strategies. Describe the type of innovative methods that may be used to enhance COTC activities including ways of interacting with stakeholders or identified end-users of materials.

Describe plans of how the COTC investigators will be able to access the effectiveness of their developed products and whenever possible.

Describe how the COTC will interact with Center investigators and the Administrative Core to develop materials and assist with the overall goals of the Center.

Describe how the COTC will develop, enhance, and ensure a productive working relationship between the community and Children's Center researchers.

Letters of Support: Include letters of support where appropriate to demonstrate collaborations, access to resources, institutional commitment, etc.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide, with the following modification:

Each Children Center application is expected to include a data sharing plan to facilitate data sharing with other Centers, federal researchers, the public and key stake holders. Applicants are expected to provide a plan to make all data resulting from an agreement under this FOA available in a format and with documentation/metadata such that they may be used by others in the scientific community. This includes data first produced under the award, i.e., from observations, analyses, or model development collected or used under the agreement. Applicants who plan to develop or enhance databases containing proprietary or restricted information are expected to provide, within the two pages, a strategy to make the data widely available, while protecting privacy or property rights.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report (Community Outreach and Translation Core)

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

PHS 398 Cumulative Inclusion Enrollment Report (Community Outreach and Translation Core)

When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report

as described in the SF424 (R&R) Application Guide.

Facility/Service Core

When preparing your application in ASSIST, use Component Type 'FSC.'

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions, as noted.

SF424 (R&R) Cover (Facility/Service Core)

- Complete only the following fields:
- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Facility/Service Core)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Facility/Service Core)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Facility/Service Core)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Facility/Service Core)

In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Core Lead' and provide a valid eRA Commons ID in the Credential field.

- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Facility/Service Core)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Facility/Service Core)

Specific Aims: State the specific aims of the Facility/Service Core

Research Strategy:

Each Center is encouraged to make use of existing Core services and resources available through their institution. New Cores should be proposed only if they are not available through existing services or facilities. Each new Core proposed must serve at least two research projects and provide a technique, service, or instrumentation that will enhance ongoing research efforts. Describe the function of the core as a resource to the program. This section must clearly present the facilities, techniques, and professional skills that the core will provide. As justification for the core, briefly indicate the specific Research Projects that will use the resources of the core. A Facility/Service Core is principally designed as a service or resource component; it would be highly unusual to include research in a core (a possible exception would be methodology development).

Describe the role of the core as a resource to the program as a whole. Discuss ways in which these centralized services will produce an economy of effort and/or savings in overall costs compared to their inclusion as part of each project in the program. To aid in the review of the application, it is recommended that the application include, in tabular form, information concerning the research projects that each facility core unit would serve and the proportion of the cost of the facility core unit associated with each research project involved.

Letters of Support: Include letters of support where appropriate to demonstrate collaborations, access to resources, institutional commitment, etc.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide.

Each Children Center application is expected to include a data sharing plan to facilitate data sharing with other Centers, federal researchers, the public and key stake holders. Applicants are expected to provide a plan to make all data resulting from an agreement under this FOA available in a format and with documentation/metadata such that they may be used by others in the scientific community. This includes data first produced under the award, i.e., from observations, analyses, or model development collected or used under the agreement. Applicants who plan to develop or enhance databases containing proprietary or restricted information are expected to provide, within the two pages, a strategy to make the data widely available, while protecting privacy or property rights.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report (Facility/Service Core)

Not Applicable.

PHS 398 Cumulative Inclusion Enrollment Report (Facility/Service Core)

Not Applicable

Research Projects

When preparing your application in ASSIST, use Component Type ‘Project.’

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions,

as noted.

SF424 (R&R) Cover (Research Projects)

- Complete only the following fields:
- Applicant Information
- Type of Applicant (optional)
- Descriptive Title of Applicant's Project
- Proposed Project Start/Ending Dates

PHS 398 Cover Page Supplement (Research Projects)

Enter Human Embryonic Stem Cells in each relevant component.

Research & Related Other Project Information (Research Projects)

Human Subjects: Answer only the 'Are Human Subjects Involved?' and 'Is the Project Exempt from Federal regulations?' questions.

Vertebrate Animals: Answer only the 'Are Vertebrate Animals Used?' question.

Project Narrative: Do not complete. Note: ASSIST screens will show an asterisk for this attachment indicating it is required. However, eRA systems only enforce this requirement in the Overall component and applications will not receive an error if omitted in other components.

Project /Performance Site Location(s) (Research Projects)

List all performance sites that apply to the specific component.

Note: The Project Performance Site form allows up to 300 sites, prior to using additional attachment for additional entries.

Research & Related Senior/Key Person Profile (Research Projects)

- In the Project Director/Principal Investigator section of the form, use Project Role of 'Other' with Category of 'Project Lead' and provide a valid eRA Commons ID in the Credential field.
- In the additional Senior/Key Profiles section, list Senior/Key persons that are working in the component.
- Include a single Biographical Sketch for each Senior/Key person listed in the application regardless of the number of components in which they participate. When a Senior/Key person is listed in multiple components, the Biographical Sketch can be included in any one component.
- If more than 100 Senior/Key persons are included in a component, the Additional Senior Key Person attachments should be used.

Budget (Research Projects)

Budget forms appropriate for the specific component will be included in the application package.

Note: The R&R Budget form included in many of the component types allows for up to 100 Senior/Key Persons in section A and 100 Equipment Items in section C prior to using attachments for additional entries. All other SF424 (R&R) instructions apply.

PHS 398 Research Plan (Research Projects)

Specific Aims: State the aims for the project. Specific aims should be built around serving the goals of the program project.

Research Strategy:

The Research Project must be pertinent to the central goal of the program.

The Research project should represent both a separate and an interdependent research effort. The benefits associated with being part of the program project must also be addressed.

Human Subjects Protections: The following should be included *in addition to the information requested in the SF 424 (R&R) Application Guide*.

EPA Human Subjects Research Statement (HSRS)

All human research studies conducted or supported by EPA are governed by EPA regulations at 40 CFR Part 26 (Protection of Human Subjects; http://www.gpo.gov/fdsys/pkg/CFR-2010-title40-vol1/xml/CFR-2010-title40-vol1-part26.xml (http://www.gpo.gov/fdsys/pkg/CFR-2010-title40-vol1/xml/CFR-2010-title40-vol1-part26.xml)). This includes the Basic Federal Policy for the Protection of Human Research Subjects, also known as the Common Rule, at subpart A and additional prohibitions and special protections for pregnant women, nursing women, and children in research conducted or supported by EPA at subparts B, C, and D. Depending upon the type of research being conducted, additional subparts of 40 CFR Part 26 may be relevant.

Procedures for the review and oversight of human research subject to 40 CFR Part 26 are also provided in EPA Order 1000.17 Change A1 (http://www.epa.gov/phre/pdf/epa-order-1000_17-a1.pdf (http://www.epa.gov/phre/pdf/epa-order-1000_17-a1.pdf)). These include review of projects for EPA-supported human research by the EPA Human Subjects Research Review Official (HSRRO). EPA Order 1000.17 Change A1 requires preliminary approval by the HSRRO of all proposed EPA-supported human research before the agreement can be entered into. Additional requirements must be met and final approval received from the HSRRO before the research can begin. When reviewing human observational exposure studies, EPA Order 1000.17 Change A1 requires the HSRRO to apply the principles described in the SEAOES document (http://www.epa.gov/nerl/sots/SEAOES_doc20080707.pdf (http://www.epa.gov/nerl/sots/SEAOES_doc20080707.pdf)) and grant approval only to studies that adhere to those principles.

All applications submitted under this FOA must include a HSRS as described below. Please use the definitions below to determine whether the proposed research involves human subjects, and then prepare a HSRS as explained below in the “HSRS Requirements” section.

Definitions (from 40 CFR Part 26 Subparts A, B, and C) to determine the involvement of human subjects in proposed research:

- "Human subject" means a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.
- "Intervention" includes both physical procedures by which data are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.
- "Interaction" includes communication or interpersonal contact between investigator and subject.
- "Private information" includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record).
- "Individually identifiable" means the identity of the subject is or may readily be ascertained by the

investigator or associated with the information.

- "Research involving the intentional exposure of a human subject" means a study of a substance in which the exposure to the substance experienced by a human subject participating in the study would not have occurred but for the human subject's participation in the study. Research involving intentional human exposures has additional requirements based upon the 2004 NRC Report "Intentional Human Dosing Studies for EPA Regulatory Purposes" (http://www.nap.edu/catalog.php?record_id=10927 (http://www.nap.edu/catalog.php?record_id=10927)) See Sections 9 - 15.
- "Observational research" means any human research that does not meet the definition of research involving intentional exposure of a human subject.

Human Subjects Research Statement (HSRS) Requirements

If the proposed research does not involve human subjects as defined above, provide the following statement in your application package as your HSRS: "The proposed research does not involve human subjects." Applicants should provide a clear justification about how the proposed research does not meet the definition (for example, all samples come from deceased individuals OR samples are purchased from a commercial source and provided without identifiers, etc).

If the proposed research does involve human subjects, then include in your application package a HSRS that addresses each applicable section listed below, referencing the specific location of the information in the Research Plan, providing the information in the HSRS, or explaining why the section does not apply to the proposed research. (Not all will apply.) Please use the definitions provided above to ensure consistency in the interpretation of terminology. Do not exceed six consecutively numbered, 8.5x11-inch pages of single-spaced, standard 12-point type with 1-inch margins.

NOTE: Before EPA approves any research involving human subjects, the requirements of the regulations at 40 CFR Part 26 must be met. Also, before EPA approves human observational exposure research, EPA will examine it to ensure consistency with the SEAOES Principles. The federal Office for Human Research Protections requires that federally funded human subjects research only be conducted at facilities covered by a Federalwide Assurance (FWA). An FWA is a document that designates the Institutional Review Board that will review and oversee the research, specifies the ethical principles under which the research will be conducted, and names the individuals who will be responsible for the proper conduct of the research. The factors below are not intended to be exhaustive of all those needed for the HSRRO to provide the final approval necessary for research to be conducted, but provide a basis upon which the HSRRO may grant the conditional approval necessary for the funding process to begin.

Items 1 – 8 must be completed for all studies involving human subjects. (For studies involving intentional exposures, also complete Items 9 -15.)

(1) Human subjects involvement, characteristics, and design.

(a) Describe and justify the proposed involvement of human subjects in the work being proposed.

(b) Describe the characteristics of the subject population, including their anticipated number, age range, and health status if relevant.

(c) Describe and justify the sampling plan, as well as the recruitment and retention strategies and the criteria for inclusion or exclusion of any subpopulations.

(d) Describe the research material that will be obtained from or about living individuals in the form of data, specimens, or records.

(e) List any collaborating sites where human subjects research will be performed, and describe the role of those

sites and collaborating investigators in the research.

(f) Describe and justify any compensation being provided to subjects for their participation in the research.

(g) Describe the plan for communicating individual and/or aggregate research results to participants, if relevant.

(2) Potential risks to subjects.

(a) Describe the potential risks to human subjects (physical, psychological, financial, legal, or other) and assess their likelihood and seriousness to the human subjects.

(3) Adequacy of protection against risks.

(a) Describe planned procedures for protecting against or minimizing potential risks and assess their likely effectiveness.

(b) Describe planned procedures for the process of obtaining and maintaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent.

(c) If waiver of some or all of the elements of informed consent or of documentation of consent will be sought, provide justification for the waiver.

(d) Where appropriate, discuss the plans for ensuring necessary medical or professional intervention in the event of adverse effects to subjects.

(4) Protection of vulnerable groups, see 40 CFR Part 26, subparts C & D.

(a) Explain the rationale for the involvement of any vulnerable populations, including pregnant women, fetuses, and children if relevant.

(b) Describe the additional protections in place, if any, for protecting vulnerable populations included in the research.

(c) If children are included in the research, describe the process for obtaining parental permission and child assent if relevant.

(5) Protection of privacy and confidentiality.

(a) Describe how data, specimens, and/or records will be collected, managed, and protected, including at collaborating sites, if any, as well as at the primary site.

(b) Indicate who will have access to individually identifiable private information about human subjects.

(c) Describe any additional procedures for the protection of privacy and confidentiality of the human research subjects.

(d) Discuss any mandatory reporting requirements with the potential to come into play during the conduct of the research and describe how these will be communicated to participants if relevant.

(e) Discuss the potential of the research to obtain information about third parties and describe how this will be handled if it occurs.

(6) Relationship between researcher and community.

(a) If the research will take place in a community setting, describe the procedures in place for defining the community, obtaining its involvement in the research, and establishing and maintaining trust.

(7) Potential benefits of the research to the participants and others.

(a) Discuss the potential benefits of the research to the research participants and others.

(b) Discuss why the risks to subjects are reasonable in relation to the anticipated benefits.

(8) Importance of the knowledge to be gained.

(a) Discuss the importance of the knowledge to be gained as a result of the proposed research.

(b) Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that reasonably may be expected to result.

The following sections are to be completed for projects involving the intentional exposure of a human subject. Note that intentional exposure of children, pregnant women or nursing women is prohibited, according to 40 CFR Part 26, subpart B. If your application does not involve intentional exposures of humans, you may enter "non-applicable" for Sections 9 – 15.

(9) Projects involving intentional exposure of human subjects should only be considered if they have the potential of providing a clear health or environmental benefit or if acquisition of such information is not obtainable by any other means. In no case should the exposure cause lasting harm to study participants.

(a) Provide justification, in advance of being conducted, that the study could contribute to addressing an important scientific question that cannot be resolved on the basis of animal data or other study;

(b) Discuss how the study is designed in accordance with current scientific standards and practices to i) address the research question, ii) include representative study populations for the endpoint in question, and iii) meet requirements for adequate statistical power;

(c) Discuss how the study will be conducted in accordance with recognized good clinical practices, including appropriate monitoring for safety; and

(d) Confirm that the grantee will report comprehensively to their EPA Project Officer, providing the full study protocol, detailed analyses of the data and report any adverse events promptly.

(10) Value of Studies that Seek to Provide a Potential Public Health or Environmental Benefit

(a) Discuss the constitution of the IRB and their ability to consider whether a study has the potential of providing a clear health or environmental benefit to the community.

(11) Criteria for Scientific and Ethical Acceptability

(a) Confirm that the following necessary conditions for scientifically and ethically acceptable intentional human dosing studies have been satisfied:

(i) prior animal studies and, if available, human observational studies;

(ii) a demonstrated need for the knowledge to be obtained from intentional human dosing studies;

(iii) justification and documentation of a research design and statistical analysis that are adequate to address an important scientific question, including adequate power to detect appropriate effects;

(iv) an acceptable balance of risks and benefits, and minimization of risks to participants;

(v) equitable selection of participants;

(vi) free and informed consent of participants; and

(vii) review by an appropriately constituted IRB.

(12) Participant Selection Criteria

(a) Discuss how the project design ensures that the following conditions are met in selecting research participants: (i) Selection should be equitable; (ii) Selection of persons from vulnerable populations must be convincingly justified in the protocol, which also must justify the measures to be taken to protect those participants; (iii) Selection of individuals with conditions that put them at increased risk for adverse effects in such studies must be convincingly justified in the protocol, which also must justify the measures that investigators will use to decrease the risks to those participants to an acceptable level.

(13) Payment for Participation

(a) Discuss how IRBs, all relevant review boards, investigators, and research sponsors should ensure that payments to participants in intentional human dosing studies are neither so high as to constitute undue inducement nor so low as to be attractive only to individuals who are socio-economically disadvantaged. Proposed levels of and purposes for remuneration (e.g., time, inconvenience, and risk) should be scrutinized in light of the principles of justice and respect for persons.

(14) Best Practices in Informed Consent

(a) Discuss the proposed process regarding informed consent in intentional human dosing studies and how it compares to best practices.

(15) Compensation for Research-Related Injuries

(a) Discuss how you ensure that participants receive needed medical care for injuries incurred in the study, without cost to the participants.

Resource Sharing Plan: Individuals are required to comply with the instructions for the Resource Sharing Plans (Data Sharing Plan, Sharing Model Organisms, and Genome Wide Association Studies (GWAS)) as provided in the SF424 (R&R) Application Guide., with the following modification.

Each Children Center application is expected to include a data sharing plan to facilitate data sharing with other Centers, federal researchers, the public and key stake holders. Applicants are expected to provide a plan to make all data resulting from an agreement under this FOA available in a format and with documentation/metadata such that they may be used by others in the scientific community. This includes data first produced under the award, i.e., from observations, analyses, or model development collected or used under the agreement. Applicants who plan to develop or enhance databases containing proprietary or restricted information are expected to provide, within the two pages, a strategy to make the data widely available, while protecting privacy or property rights.

Appendix: Do not use the Appendix to circumvent page limits. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

Planned Enrollment Report (Research Projects)

When conducting clinical research, follow all instructions for completing Planned Enrollment Reports as described in the SF424 (R&R) Application Guide.

PHS 398 Cumulative Inclusion Enrollment Report (Research Projects)

When conducting clinical research, follow all instructions for completing Cumulative Inclusion Enrollment Report as described in the SF424 (R&R) Application Guide.

3. Submission Dates and Times

Part I. Overview Information contains information about Key Dates. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission.

Organizations must submit applications to Grants.gov (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11128) (the online portal to find and apply for grants across all Federal agencies) using ASSIST or other electronic submission systems. Applicants must then complete the submission process by tracking the status of the application in the eRA Commons (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123), NIH's electronic system for grants administration.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

4. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review. (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11142)

5. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the *NIH Grants Policy Statement (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120)*.

Pre-award costs are allowable only as described in the *NIH Grants Policy Statement (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11143)*.

For EPA awards: Executive Order 12372, "Intergovernmental Review of Federal Programs," does not apply to the EPA's Office of Research and Development's research and training programs unless EPA has determined that the activities that will be carried out under the application (a) require an Environmental Impact Statement (EIS), or (b) do not require an EIS but will be newly initiated at a particular site and require unusual measures to limit the possibility of adverse exposure or hazard to the general public, or (c) have a unique geographic focus and are directly relevant to the governmental responsibilities of a State or local government within that geographic area.

If EPA determines that Executive Order 12372 applies to an application, the applicant must follow the procedures in 40 CFR Part 29. The applicant must notify their state's single point of contact (SPOC). To determine whether their state participates in this process, and how to comply, applicants should consult http://www.whitehouse.gov/omb/grants_spoc/ (http://www.whitehouse.gov/omb/grants_spoc/). If an applicant is in a State that does not have a SPOC, or the State has not selected research and development grants for intergovernmental review, the applicant must notify directly affected State, area wide, regional and local entities of its application.

EPA will notify the successful applicant(s) if Executive Order 12372 applies to its application prior to award.

EPA awards are subject to the following funding restrictions:

EPA awards funds to one eligible applicant as the recipient even if other eligible applicants are named as partners or co-applicants or members of a coalition or consortium. The recipient is accountable to EPA for the proper expenditure of funds. IF the grant is funded by both NIEHS and EPA, then the recipient is accountable to EPA and NIEHS for the proper expenditure of funds.

All award decisions are subject to the availability of funds. In accordance with the Federal Grant and Cooperative Agreement Act, 31 U.S.C. 6301 et seq., the primary purpose of an assistance agreement is to accomplish a public purpose of support or stimulation authorized by federal statute, rather than acquisition for the direct benefit or use of the Agency. In issuing a grant, the EPA and NIEHS anticipate that there will be no substantial EPA involvement in the design, implementation, or conduct of the research. However, the EPA and

NIEHS will monitor research progress through a variety of means, including annual reports provided by grantees and other contacts, as well as site visits with the PD/PI or MPI/PI).

EPA funding may be used to provide subgrants or subawards of financial assistance, which includes using subawards or subgrants to fund partnerships, provided the recipient complies with applicable requirements for subawards or subgrants including those contained in 40 CFR Parts 30 or 31, as appropriate. Applicants must compete contracts for services and products, including consultant contracts, and conduct cost and price analyses to the extent required by the procurement provisions of the regulations at 40 CFR Parts 30 or 31, as appropriate. The regulations also contain limitations on consultant compensation. Applicants are not required to identify subawardees/subgrantees and/or contractors (including consultants) in their application. However, if they do, the fact that an applicant selected for award has named a specific subawardee/subgrantee, contractor, or consultant in the application EPA selects for funding does not relieve the applicant of its obligations to comply with subaward/subgrant and/or competitive procurement requirements as appropriate. Please note that applicants may not award sole source contracts to consulting, engineering or other firms assisting applicants with the application based solely on the firm's role in preparing the application.

Successful applicants cannot use subgrants or subawards to avoid requirements in EPA grant regulations for competitive procurement by using these instruments to acquire commercial services or products from for-profit organizations to carry out its assistance agreement. The nature of the transaction between the recipient and the subawardee or subgrantee must be consistent with the standards for distinguishing between vendor transactions and subrecipient assistance under Subpart B Section .210 of OMB Circular A-133, and the definitions of subaward at 40 CFR 30.2(ff) or subgrant at 40 CFR 31.3, as applicable. Neither EPA nor NIEHS will be a party to these transactions. Applicants acquiring commercial goods or services must comply with the competitive procurement standards in 40 CFR Part 30 or 40 CFR Part 31.36 and cannot use a subaward/subgrant as the funding mechanism.

Each proposed project must be able to be completed within the project period and with the initial award of funds. Applicants should request the entire amount of money needed to complete the project. Recipients should not anticipate additional funding beyond the initial award of funds for a specific project.

EPA Award Procedures: Applicants to be recommended for EPA funding will be required to submit additional information and an electronic version of the revised project abstract. They may also be asked to provide responses to comments or suggestions offered by the peer reviewers and/or a revised budget. EPA Project Officers will contact the PD(s)/PI(s) to obtain these materials. Before or after an award, applicants may be required to provide additional quality assurance documentation.

EPA Quality Assurance Documentation: For Centers with projects involving data collection or processing, conducting surveys, environmental measurements, modeling, or the development of environmental technology (whether hardware-based or via new techniques), EPA will require the recipient to submit a Quality Management Plan and other appropriate quality assurance documentation on the processes that will be used to assure that results of the research satisfy the intended project objectives. This is not required for application submission, but will be required for any applications that EPA chooses to recommend for funding. More detailed information on requirements can be found at http://www.epa.gov/ncer/guidance/qa.html (http://www.epa.gov/ncer/guidance/qa.html).

Generally, applicants are not prohibited from submitting the same or virtually the same application to EPA under multiple competitions, if appropriate. However, if an applicant does so, and the application is selected for award under another competition, that may affect their ability to receive an award under this competition for that application.

6. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application

Guide. Paper applications will not be accepted.

For information on how your application will be automatically assembled for review and funding consideration after submission go to: http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf (http://grants.nih.gov/grants/ElectronicReceipt/files/Electronic_Multi-project_Application_Image_Assembly.pdf).

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit Applying Electronically (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11144).

Important reminders:
All PD(s)/PI(s) and component Project Leads must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile Component of the SF424(R&R) Application Package**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH.

The applicant organization must ensure that the DUNS number it provides on the application is the same number used in the organization's profile in the eRA Commons and for the System for Award Management (SAM). Additional information may be found in the SF424 (R&R) Application Guide.

See more tips (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11146) for avoiding common errors.

Upon receipt, applications will be evaluated for completeness by the Center for Scientific Review and responsiveness by the National Institute of Environmental Health Sciences. Applications that are incomplete and/or nonresponsive will not be reviewed.

In order to expedite review, applicants are requested to notify the NIEHS Scientific Review Officer, Dr. Bass, by email at bass@niehs.nih.gov (mailto:bass@niehs.nih.gov) when the application has been submitted. Please include the FOA number and title, PD/PI name, and title of the application.

Budget for Submissions to EPA

Please note that when formulating budgets for applications, applicants must not include management fees or similar charges in excess of the direct costs and indirect costs at the rate approved by the applicants cognizant audit agency, or at the rate provided for by the terms of the agreement negotiated with EPA. The term "management fees or similar charges" refers to expenses added to the direct costs in order to accumulate and reserve funds for ongoing business expenses, unforeseen liabilities, or for other similar costs that are not allowable under EPA assistance agreements. Management fees or similar charges may not be used to improve or expand the project funded under this agreement, except to the extent authorized as a direct cost of carrying out the scope of work.

All costs incurred under this program must be allowable under 40 CFR 30.27 or 40 CFR 31.22, as applicable, and the applicable Office of Management and Budget (OMB) Cost Circulars: 2 CFR Part 225 (State, local, or Indian tribal governments), 2 CFR Part 230 (non-profit organizations), or 2 CFR Part 220 (Educational institutions). Copies of these circulars can be found at http://www.whitehouse.gov/omb/circulars/ (http://www.whitehouse.gov/omb/circulars_default). In accordance with applicable law, regulation, and policy, any recipient of funding must agree to comply with restrictions on using assistance funds for unauthorized lobbying, fund-raising, or political activities (i.e., lobbying members of Congress or lobbying for other federal grants, cooperative agreements, or contracts). Funds generally cannot be used to pay for travel by federal agency staff. Proposed project activities must also comply with all state and federal regulations applicable to the project area. The applicant must also review the funding opportunity announcement or any other programmatic funding

restrictions applicable to this program. If awarded funding, the recipient must refer to the terms and conditions of its award for other funding restrictions applicable to its award. It is the responsibility of the recipient to ensure compliance with these requirements.

Confidentiality

By submitting an application to this Funding Opportunity Announcement, the applicant grants the EPA permission to make limited disclosures of the application to technical reviewers both within and outside the Agency for the express purpose of assisting the Agency with evaluating the application. Information from a pending or unsuccessful application will be kept confidential to the fullest extent allowed under law; information from a successful application may be publicly disclosed to the extent permitted by law.

EPA recommends that you do not include confidential business information ("CBI") in your application. However, if confidential business information is included, it will be treated in accordance with 40 CFR 2.203. Applicants must clearly indicate which portion(s) of their application they are claiming as CBI. EPA will evaluate such claims in accordance with 40 CFR Part 2. If no claim of confidentiality is made, EPA is not required to make the inquiry to the applicant otherwise required by 40 CFR 2.204(c)(2) prior to disclosure. The Agency protects competitive applications from disclosure under applicable provisions of the Freedom of Information Act prior to the completion of the competitive selection process.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in NOT-OD-13-030 (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-030.html).

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. As part of the NIH mission (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11149), all applications submitted to the NIH in support of biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Overall Impact - Overall

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria - Overall Program

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and

training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria -Overall Program

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Does the Center consist of a cohesive and multidisciplinary focus? Does a coordinated interrelationship exist between the research projects and cores? Are the components of the Center related to the common theme of the Center?

What is the scientific gain of combining the component parts into a Center?

For new applications, is there evidence of the degree of synergy (degree of interaction, collaborative research opportunities) that will be stimulated by the Center? How do the research projects and cores relate to the central theme and the ability of the Center to meet its long range goals?

Will the specific scientific objectives of each project benefit significantly from, or depend upon collaborative interactions with other projects in the program (i.e., objectives that can be uniquely accomplished, specific contributions to the accomplishments of objectives in other projects, objectives that can be accomplished with greater effectiveness and/or economy of effort, etc.)?

Have Center investigators adequately addressed the criteria required for each Essential Element (Career Development Plan, the inclusion of a Children’s Health Specialist, and Community Engagement)?

Have the investigators adequately conceptualized the Center’s expected results and potential benefits to their community of concern or the broader public?

If SDH/non-chemical stressor(s) are proposed as a modifying factor(s) for chemical stressor(s)are they appropriate, relevant and well described?

Review Criteria for Individual Research Projects

Scored Review Criteria - Projects

Reviewers will consider each of the review criteria below in the determination of scientific merit, and give a separate score for each. A project does not need to be strong in all categories to be judged likely to have major scientific impact.

Significance

Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI , do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria -Projects

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

If the Research Project(s) include(s) Community Based Participatory Research as an aspect of the Project, then the following criteria will be included in the evaluation.

Are the Center's activities appropriate to the needs of the community involved?

Is the research proposed focused on children's environmental health or the exposure under investigation?

Is a mechanism present for regular communication and coordination among investigators and relevant stakeholders with concerns focused on children's environmental health or environmental exposures?

Are the stakeholders involved in other aspects of the Center?

Does a productive working relationship exist between Center investigators and community stakeholders?

Will information be adequately disseminated?

Overall Impact - Administrative Core

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the Administrative Core to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the core proposed).

Review Criteria - Administrative Core

Reviewers will consider each of the criteria below in the determination of scientific and technical merit.

What is the decision-making process within the proposed Center? Is it adequate for the evaluation of research productivity, allocation of funds, and management of the resources? Are procedures clearly outlined to measure and track Center goals, outputs and outcomes?

How will the Administrative Core promote joint planning and evaluation activities as well as collaborations and interactions among different Research Projects of the Centers?

What are the academic environment and resources in which the research will be conducted? Is there available and appropriate space, equipment, human subjects, animals, or other resources as required for potential interaction with scientist(s) from other departments to complete the scope of work as proposed?

What is the institutional commitment to the Center, including fiscal responsibility and management capability of the institution to assist the PD/PI and his/her staff in following DHHS, PHS, NIH and EPA policy?

Are the approach, procedures, and controls for ensuring timely and efficient expenditure of awarded grant funds well defined and acceptable? Is the approach for ensuring successful achievement of project objectives adequate and in accordance with the research projects' schedule and milestones?

If the community engagement is discussed as a function of the Administrative Core, then the following criteria must be included in the evaluation. Are the Center's activities appropriate to the needs of the community involved? How will the Center facilitate regular communication and coordination among investigators and relevant stakeholders with concerns focused on children's environmental health or environmental exposures? How are the stakeholders involved in other aspects of the Center and how they will interact with Center activities and develop a relationship with the Center Investigators? If a Community Advisory Board is proposed, does it have appropriate and adequate membership to be successful?

Career Development

What are the Center’s plans for supporting the research career development of new junior level faculty members?

Does the Center’s plan provide high quality mentoring of junior investigators so as to foster their research careers?

Is a mentoring plan proposed, and if so, is the plan adequate?

What are the Center’s plans for monitoring the progression and development of new junior level faculty members?

Health Specialist

Is/are the Health Specialist(s) appropriately qualified?

Is the Health Specialist an active researcher from a discipline that traditionally has direct contact with young children in a treatment-based environment with expertise directly relevant to the Center’s theme?

Overall Impact - Community Outreach and Translation Core

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the Community Outreach and Translation Core to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the core proposed).

Review Criteria - Community Outreach and Translation Core

Reviewers will consider each of the criteria below in the determination of scientific and technical merit.

Are the plans for the establishment of a Community Outreach and Translation Core appropriate and adequate for success?

Have particular community groups or organizations been identified and are their support and commitment adequate and appropriate?

Are the detailed plans and approaches for dissemination from the Core adequate for success?

Overall Impact - Facility/Service Core

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the Facility/Service Core to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the core proposed).

Review Criteria - Facility/Service Core

Reviewers will consider each of the criteria below in the determination of scientific and technical merit.

What is the Core's utility to Center investigators? Does each Core provide services for two or more research projects that are judged to have substantial merit?

What is the quality of the facility or services provided?

What are the availability and/or adequacy of the physical space, laboratory, clinic and/or equipment proposed for the Core?

What is the cost-effectiveness of the service provided?

Are the qualifications of the personnel involved, their experience, and commitment to the Core appropriate?

Additional Review Criteria - Overall Program, Administrative Core, Community Outreach and Translation Core, Facility/Service Core(s), and Projects

Protections for Human Subjects

For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11175).

Inclusion of Women, Minorities, and Children

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11174).

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11150).

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

Not Applicable

Renewals

For Renewals, the committee will consider the progress made in the last funding period.

Has sufficient progress been made in the last funding period relative to the original goals of the Program Project and objectives of each Research Project and Core?

Does progress made during the previous funding period demonstrate an acceptable level of integration between the Research Projects and Cores?

Were the previous specific aims accomplished, and are the proposed research goals logical extensions of work

during the current funding period?

Has scientific synergy occurred, as indicated by joint publications and new collaborative aims and/or projects?

Is there adequate justification for adding or deleting new Research Projects and/or Cores?

Revisions

Not Applicable

Additional Review Considerations - Overall Program

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

Not Applicable

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the following Resource Sharing Plans, or the rationale for not sharing the following types of resources, are reasonable: 1) Data Sharing Plan (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11151); 2) Sharing Model Organisms (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11152); and 3) Genome Wide Association Studies (GWAS) (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11153).

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s), convened by NIEHS in accordance with NIH peer review policy and procedures (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11154), using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications:

- May undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.
- Will receive a written critique.

Appeals (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-064.html) of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned

to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this FOA. Following initial peer review, recommended applications will receive a second level of review by the National Environmental Health Sciences Advisory Council . The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project to program priorities.
- Program balance.
- Results of EPA programmatic review.
- Results from the EPA HSRRO's assessment of applicant's HSRS (where applicable).

NIEHS-EPA Joint Funding Decision

Since these applications will be jointly funded by both agencies, both agencies program and grants management staff will use the above considerations in making funding recommendations to NIEHS leadership and the National Center for Environmental Research senior management for joint final funding decisions.

EPA Review and Selection Process Post Peer Review:

EPA's internal review criteria for all applications under consideration for EPA support:

Applications discussed and receiving numerical impact scores as a result of the NIEHS peer review will undergo an internal programmatic review, as described below, conducted by technical experts from the EPA, including individuals from the Office of Research and Development (ORD) and program and regional offices involved with the science or engineering proposed. All other applications are automatically declined.

After the peer review, those applicants receiving numerical impact scores will be asked to provide additional information for the programmatic review pertaining to the proposed PD/PI (in the case of Multiple-PD/PI applications, the Lead/Contact PD/PI's) "Past Performance and Reporting History." The applicant must provide the EPA Project Officer with information on the proposed Lead/Contact PD/PI's past performance and reporting history under prior Federal agency assistance agreements (assistance agreements include grants and cooperative agreements but not contracts) in terms of: (i) the level of success in managing and completing each agreement, and (ii) history of meeting the reporting requirements under each agreement.

This information is required only for the proposed Lead/Contact PD/PI's performance under Federal assistance agreements initiated within the last three years that were similar in size and scope to the proposed project.

The specific information required for each agreement is shown below, and must be provided within one week of EPA's request. A maximum of three pages will be permitted for the response; excess pages will not be reviewed. Note: If no prior past performance information and/or reporting history exists, you will be asked to so state.

1. Name of Granting Agency.

2. Grant number.

3. Grant title.

4. Brief description of the grant.

5. A description of how the agreement is similar in size and scope to the proposed project and whether or not it was successfully managed and completed; if not successfully managed and completed, provide an explanation.

6. Information relating to the proposed / Lead/Contact PD/PI's past performance in reporting on progress

towards achieving the expected results (outputs/outcomes) under the agreement. Include the history of submitting timely progress/final technical reports, describe how progress towards achieving the expected results was reported/documented, and if such progress was not being made, provide an explanation of whether, and how, this was reported.

7. Total (all years) grant dollar value.

8. Project period.

9. Technical contact (project officer), telephone number, and Email address (if available).

The purpose of the programmatic review is to ensure an integrated research portfolio for the Agency and help determine which applications to recommend for award. In conducting the programmatic review, the EPA will consider information provided by the applicant and may consider information from other sources, including prior and current grantors and agency files.

The EPA internal programmatic review panel will assess (EPA considers relevance more important than the Lead/Contact PD/PI's past performance):

1. The relevance of the proposed science to EPA research priorities, including alignment with ORD's Sustainable and Healthy Communities Programs Research Priorities at http://www2.epa.gov/epa-research/sustainable-and-health-communities-strategic-research-action-plan-2012-2016 (http://www2.epa.gov/epa-research/sustainable-and-health-communities-strategic-research-action-plan-2012-2016).

2. The proposed Lead/Contact PD/PI's past performance [under Federal agency assistance agreements (assistance agreements include grants and cooperative agreements but not contracts) initiated within the last three years that were similar in size and scope to the proposed project] in two areas: First, in successfully managing and completing these prior Federal assistance projects, including whether there is a satisfactory explanation for any lack of success; and Second, in reporting progress toward achieving results under these agreements, including the proposed Lead/Contact PD/PI's history of submitting timely progress/final technical reports that adequately describe the progress toward achieving the expected results (outputs/outcomes) under the agreements. Any explanation of why progress toward achieving the results was not made will also be considered. Applicants whose proposed Lead/Contact PD/PI has no relevant past performance and/or reporting history, or for whom this information is not available, will be evaluated neither favorably nor unfavorably on these elements.

EPA Human Subjects Research Statement (HSRS) Review

Applications being considered for funding after the EPA Programmatic Review that involve human subjects research studies will have their HSRS reviewed by EPA's Human Subjects Research Review Official (HSRRO) prior to award. The HSRRO will review the information provided in the HSRS and the Research Plan to determine if the ethical treatment of human subjects is described in a manner appropriate for conditional approval to be granted.

Final EPA funding decisions are made by the NCER Director based on the results of the peer review, the internal programmatic review and, where applicable, the EPA HSRRO's assessment of the applicant's HSRS (see Section IV). In addition, in making the final funding decisions, the NCER Director may also consider program balance and available funds. Applicants selected for funding will be required to provide additional information listed below under "Award Notices." The application will then be forwarded to EPA's Grants and Interagency Agreement Management Division for award in accordance with the EPA's procedures.

Generally, following EPA's evaluation of applications, all applicants will be notified regarding their status. Final applications and forms will be requested, as necessary, from those eligible entities whose application has been successfully evaluated and preliminarily recommended for award. Those entities will be provided with

instructions and a due date for submittal of the final application package.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11123).

Information regarding the disposition of applications is available in the *NIH Grants Policy Statement (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11156)*.

Section VI. Award Administration Information

1. Award Notices

Applications will be jointly funded by both EPA and NIH, and thus each agency will conduct its own pre-award administrative review and issue a Notice of Award (NoA) reflecting that agency's funding commitment. Program staff from both agencies will coordinate prior to award issuance.

If the application is under consideration for funding by NIH, NIH will request "just-in-time" information from the applicant as described in the *NIH Grants Policy Statement (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157)*. Separate requests for "just-in-time" information will also come from EPA to address EPA specific concerns and components (e.g. E.O. 12372 Applicability, and Past Performance and Reporting History). The applicant should address any response to the agency that has made the request, and should not assume that "just-in-time" information provided to NIH or EPA is automatically transmitted to the other agency.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the grantee's business official.

Awardees must comply with any funding restrictions described in Section IV.5. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this FOA will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11158) website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the *NIH Grants Policy Statement (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120)* as part of the NoA. For these terms of award, see the *NIH Grants Policy Statement* Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11157) and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Grantees, and Activities (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11159). More information is provided at Award Conditions and Information for NIH Grants (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11158).

Cooperative Agreement Terms and Conditions of Award

Not Applicable

Additional Notices and Requirements for EPA Funding

For EPA, the official notification of an award will be made by the Agency's Grants and Interagency Agreement Management Division. Applicants are cautioned that only a grants officer is authorized to bind the Government to the expenditure of funds; preliminary selection by the NCER Director in the Office of Research and Development does not guarantee an award will be made. For example, statutory authorization, funding, or other issues discovered during the award process may affect the ability of EPA to make an award to an applicant. The award notice, signed by an EPA grants officer, is the authorizing document and will be provided through electronic or postal mail.

Non-profit applicants that are recommended for EPA funding under this announcement are subject to pre-award administrative capability reviews consistent with Sections 8b., 8c. and 9d. of EPA Order 5700.8 - Policy on Assessing Capabilities of Non-Profit Applicants for Managing Assistance Awards (http://www.epa.gov/ogd/grants/award/5700_8.pdf (http://www.epa.gov/ogd/grants/award/5700_8.pdf)). In addition, non-profit applicants that qualify for funding may, depending on the size of the award, be required to fill out and submit to the Grants Management Office the Administrative Capabilities Form with supporting documents contained in Appendix A of EPA Order 5700.8.

Disputes related to this assistance agreement competition will be resolved in accordance with the dispute resolution procedures set forth in 70 FR 3629, 3630 (January 26, 2005) which can be found at http://www.epa.gov/ogd/competition/resolution.htm (http://www.epa.gov/ogd/competition/resolution.htm). Questions regarding disputes may be referred to the Eligibility Contact identified below.

Expectations and responsibilities of EPA/NCER grantees are summarized in this section, although the terms grant and grantee are used. See http://www.epa.gov/ncer/guidance (http://www.epa.gov/ncer/guidance) for the full terms and conditions associated with an award, including which activities require prior approval from the EPA.

a. Meetings: PDS(s)/PI(s) will be expected to budget for, and participate in, All-Investigators Meetings (also known as progress reviews) approximately once per year with EPA and NIEHS scientists and other grantees to report on research activities and discuss issues of mutual interest.

b. Approval of Changes after Award: Prior written approval of changes may be required from EPA. Examples of these changes are contained in 40 C.F.R. 30.25. Note: prior written approval is also required from the EPA Award Official for incurring costs more than 90 calendar days prior to award.

c. Human Subjects: A grant applicant must agree to meet all EPA requirements for studies using human subjects prior to implementing any work with these subjects. These requirements are given in 40 CFR Part 26. Studies involving intentional exposure of human subjects who are children or pregnant or nursing women are prohibited by Subpart B of 40 CFR Part 26. For observational studies involving children or pregnant women and fetuses please refer to Subparts C & D of 40 CFR Part 26. U.S. Department of Health and Human Services regulations at 45 CFR Part 46.101(e) have long required "... compliance with pertinent Federal laws or regulations which provide additional protection for human subjects." EPA's regulation 40 CFR Part 26 is such a pertinent Federal regulation. Therefore, the applicant's Institutional Review Board (IRB) approval must state that the applicant's study meets the EPA's regulations at 40 CFR Part 26. No work involving human subjects, including recruiting, may be initiated before the EPA has received a copy of the applicant's IRB approval of the project and the EPA has also provided approval. Where human subjects are involved in the research, the recipient must provide evidence of subsequent IRB reviews, including amendments or minor changes of protocol, as part of annual reports.

Guidance and training for investigators conducting EPA-funded research involving human subjects may be obtained here:

http://www.epa.gov/osainter/phre/support.htm (http://www.epa.gov/osainter/phre/support.htm)

http://www.epa.gov/osa/pdfs/phre/phre_course/index.htm (http://www.epa.gov/osa/pdfs/phre/phre_course

/index.htm)

d. A grant recipient must agree to comply with the Animal Welfare Act of 1966 (P.L. 89-544), as amended, 7 U.S.C. 2131-2159. The recipient must also agree to abide by the "U.S. Government Principles for the Utilization and Care of Vertebrate Animals used in Testing, Research, and Training." (50 Federal Register 20864-20865 (May 20, 1985))

* This clause applies if a research facility (defined as any school (except elementary or secondary), institution, organization or person) receives funds under a grant from a federal agency for the purpose of carrying out research, tests, or experiments involving animals.

Congress, through OMB, has instructed each federal agency to implement Information Quality Guidelines designed to "provide policy and procedural guidance...for ensuring and maximizing the quality, objectivity, utility, and integrity of information, including statistical information, disseminated by Federal agencies." The EPA's implementation may be found at http://epa.gov/quality/exmural.html#genreqts (http://epa.gov/quality/exmural.html#genreqts). These procedures may apply to data generated by grant recipients if those data are disseminated as described in the Guidelines.

EPA has the right to obtain, reproduce, publish, or otherwise use the data first produced under the awards to be made under this FOA and authorize others to receive, reproduce, publish, or otherwise use such data for Federal purposes under 40 C.F.R. § 30.36(c). In addition, pursuant to 40 C.F.R. § 30.36(d), if EPA receives a Freedom of Information Act request for research data that (1) relates to published research findings produced under an EPA award and (2) was used by the Federal Government in developing an agency action that has the force and effect of law, then EPA shall request, and the award recipient shall provide, within a reasonable time, the research data so that it may be made available to the public through procedures established under the FOIA.

In accordance with 40 CFR 31.34 (for state, local and Indian tribal governments) or 40 CFR 30.36, as applicable, EPA reserves a royalty-free, nonexclusive and irrevocable right to reproduce, publish, or otherwise use, and to authorize others to use, for Federal Government purposes, copyrighted works developed under a grant, subgrant or contract under a grant or subgrant. Examples of federal purpose include but are not limited to: (1) Use by EPA and other federal employees for official Government purposes; (2) Use by federal contractors performing specific tasks for the Government; (3) Publication in EPA documents provided the document does not disclose trade secrets (e.g. software codes) and the work is properly attributed to the recipient through citation or otherwise; (4) Reproduction of documents for inclusion in federal depositories; (5) Use by state, tribal and local governments that carry out delegated federal environmental programs as “co-regulators” or act as official partners with EPA to carry out a national environmental program within their jurisdiction; and (6) Limited use by other grantees to carry out federal grants provided the use is consistent with the terms of EPA’s authorization to the grantee to use the copyrighted material.

NIH grants policies as described in the NIH Grants Policy Statement (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120) and the Grants Compliance and Oversight (http://grants.nih.gov/grants/compliance/compliance.htm) section will apply to the applications submitted and awards made in response to this FOA. Recipients of NIH and EPA grant funds must comply with all applicable Federal statutes (such as those included in appropriations acts) regulations, and policies. Additionally, they must also comply with their institutional requirements.

Subaward and Executive Compensation Reporting: Applicants must ensure that they have the necessary processes and systems in place to comply with the sub-award and executive total compensation reporting requirements established under OMB guidance at 2 CFR Part 170 (http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=65430b8cd60ba715d7bbf033c2c00425&tpl=/ecfrbrowse/Title02/2cfr170_main_02.tpl), unless they qualify for an exception from the requirements, should they be selected for funding.

EPA Pre-Application Assistance and Communications: In accordance with EPA's Assistance Agreement

Competition Policy (EPA Order 5700.5A1), EPA staff will not meet with individual applicants to discuss draft applications, provide informal comments on draft applications, or provide advice to applicants on how to respond to ranking criteria. Applicants are responsible for the contents of their applications. However, consistent with the provisions in the announcement, EPA will respond to questions from individual applicants regarding threshold eligibility criteria, administrative issues related to the submission of the application, and requests for clarification about any of the language or provisions in the announcement. Please note that applicants should raise any questions they may have about the FOA language to the contact identified in Section VII as soon as possible so that any questions about the FOA language may be resolved prior to submitting an application. In addition, if necessary, EPA may clarify threshold eligibility issues with applicants prior to making an elgibility determination.

Website References in FOA: Any non-federal websites or website links included in this FOA are provided for application preparation and/or informational purposes only. U.S. EPA does not endorse any of these entities or their services. In addition, EPA does not guarantee that any linked, external websites referenced in this FOA comply with Section 508 (Accessibility Requirements) of the Rehabilitation Act.

Unpaid Federal Tax Liabilities and Felony Convictions for Non-Profit and For-Profit Organizations: Awards made under this announcement are subject to the provisions contained in the Consolidated Appropriations Act, 2014, Public Law 113-76, Division G, Title IV, Sections 422 and 423 regarding unpaid federal tax liabilities and federal felony convictions, which have been included in prior appropriations acts also. These provisions (and the prior ones) prohibit EPA from awarding funds made available by the Act (and the prior appropriations acts) to any for-profit or non-profit organization: (1) subject to any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability; or (2) that was convicted of a felony criminal conviction under any Federal law within 24 months preceding the award, unless EPA has considered suspension or debarment of the corporation, based on these tax liabilities or convictions, and determined that such action is not necessary to protect the Government’s interests. Non-profit or for-profit organizations that are covered by these prohibitions are ineligible to receive an award under this announcement.

Exchange Network: EPA, states, territories, and tribes are working together to develop the National Environmental Information Exchange Network, a secure, Internet- and standards-based way to support electronic data reporting, sharing, and integration of both regulatory and non-regulatory environmental data. States, tribes and territories exchanging data with each other or with EPA, should make the Exchange Network and the Agency's connection to it, the Central Data Exchange (CDX), the standard way they exchange data and should phase out any legacy methods they have been using. More information on the Exchange Network is available at www.exchangenetwork.net (http://www.exchangenetwork.net/).

EPA personnel will take appropriate actions in situations where it is determined that an applicant may have an unfair competitive advantage, or the appearance of such, in competing for awards under this announcement. Affected applicants will be provided an opportunity to respond before any final action is taken.

In accordance with EPA's Policy to Assure the Competency of Organizations Generating Environmental Measurement Data under Agency-Funded Assistance Agreements, successful applicants/recipients for awards under this competition that are expected to exceed $200,000 in federal funding that involve the generation or use of environmental data must demonstrate competency to perform such work either prior to award, or if that is not practicable or will delay the award, prior to beginning any work involving the generation or use of environmental data under the agreement. Applicants that demonstrate competency prior to award must maintain competency, as appropriate, during the award period. Applicants that do not address competency prior to award must demonstrate competency prior to beginning any work involving the generation or use of environmental data under the agreement and maintain competency, as appropriate, during the award period. A copy of the Policy is available online at http://www.gpo.gov/fdsys/pkg/FR-2013-04-29/html/2013-10043.htm (http://www.gpo.gov/fdsys/pkg/FR-2013-04-29/html/2013-10043.htm) or a copy may also be requested by contacting the person listed in

Section VII of the announcement.

3. Reporting

Awardees are expected to follow the reporting requirements listed on all Notices of Award resulting from their application. This means that awardees will be responsible for submitting progress reports, financial reports, closeout reports, etc. to each agency in the timeframe and format specified by that agency.

The awardee is responsible for reporting to both agencies any requests for prior approval that impact both Notices of Award.

NIH Reporting Requirements

When multiple years are involved, awardees will be required to submit the Non-Competing Continuation Grant Progress Report (PHS 2590 (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11160) or RPPR (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11168)) annually and financial statements as required in the *NIH Grants Policy Statement*. (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161)

A final progress report, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the *NIH Grants Policy Statement (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11161)*.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for awardees of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All awardees of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11170) on all subawards over $25,000. See the *NIH Grants Policy Statement (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11171)* for additional information on this reporting requirement.

EPA Reporting Requirements

An EPA grant recipient is expected to manage assistance agreement funds efficiently and effectively and make sufficient progress towards completing the project activities described in the research plan in a timely manner. The assistance agreement will include terms/conditions implementing this requirement.

A grant recipient must agree to provide annual progress reports, with associated summaries, and a final report with an executive summary. The executive summary will be posted on EPA/NCER's website.

A grant recipient must agree to provide copies of any peer reviewed journal article(s) resulting from the research during the project period. In addition, the recipient should notify the EPA Project Officer of any papers published after completion of the grant that were based on research supported by the grant. NCER posts references to all publications resulting from a grant on the NCER web site.

Acknowledgement of EPA Support: EPA's full or partial support must be acknowledged in journal articles, oral or poster presentations, news releases, interviews with reporters and other communications. Any documents developed under this agreement that are intended for distribution to the public or inclusion in a scientific, technical, or other journal shall include the following statement or another as specified by EPA's project officer:

This publication [article] was developed under Assistance Agreement No._____ awarded by the U.S. Environmental Protection Agency to [name of recipient]. It has not been formally reviewed by EPA. The views expressed in this document are solely those of [name of recipient or names of authors] and do not necessarily reflect those of the Agency. EPA does not endorse any products or commercial services mentioned in this publication.

A graphic that may be converted to a slide or used in other ways, such as on a poster, is located athttp://epa.gov

/ncer/guidance/star_images.html (http://epa.gov/ncer/guidance/star_images.html). EPA expects recipients to use this graphic in oral and poster presentations.

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Application Submission Contacts

eRA Commons Help Desk (Questions regarding eRA Commons registration, submitting and tracking an application, documenting system problems that threaten submission by the due date, post submission issues)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)
Finding Help Online: http://grants.nih.gov/support/index.html (http://grants.nih.gov/support/index.html)
Email: commons@od.nih.gov (mailto:commons@od.nih.gov)

Grants.gov Customer Support (http://www.grants.gov/contactus/contactus.jsp) (Questions regarding Grants.gov registration and submission, downloading forms and application packages)
Contact Center Telephone: 800-518-4726
Web ticketing system: https://grants-portal.psc.gov/ContactUs.aspx (https://grants-portal.psc.gov/ContactUs.aspx)
Email: support@grants.gov (mailto:support@grants.gov)

GrantsInfo (Questions regarding application instructions and process, finding NIH grant resources)
Telephone: 301-435-0714
Email: GrantsInfo@nih.gov (mailto:GrantsInfo@nih.gov)

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Section VIII. Other Information

Recently issued trans-NIH policy notices (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11163) may affect your application submission. A full list of policy notices published by NIH is provided in the *NIH Guide for Grants and Contracts* (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11164). All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement (http://grants.nih.gov/grants/guide/url_redirect.htm?id=11120).

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Parts 74 and 92

The EPA authority for this FOA and resulting awards is contained in the Safe Drinking Water Act, Section 1442, 42 U.S.C. 300j-1; the Toxic Substances Control Act, Section 10, 15 U.S.C. 2609; the Federal Insecticide, Fungicide, and Rodenticide Act, Section 20, 7 U.S.C. 136r; the Clean Air Act, Section 103, 42 U.S.C. 7403; the Clean Water Act, Section 104, 33 U.S.C. 1254; and the Solid Waste Disposal Act, Section 8001, 42 U.S.C. 6981. For research with an international aspect, the above statutes are supplemented, as appropriate, by the National Environmental Policy Act, Section 102(2)(F).

Applicable EPA regulations include: 40 CFR Part 30 (Uniform Administrative Requirements for Grants and Agreements with Institutions of Higher Education, Hospitals, and Other Non-Profit Organizations), 40 CFR Part 31 (Uniform Administrative Requirements for Grants and Cooperative Agreements to State and Local Governments) and 40 CFR Part 40 (Research and Demonstration Grants). Applicable OMB Circulars include: OMB Circular A-21 (Cost Principles for Educational Institutions) relocated to 2 CFR Part 220 (http://www.access.gpo.gov/nara/cfr/waisidx_08/2cfr220_08.html (http://www.access.gpo.gov/nara/cfr/waisidx_08/2cfr220_08.html)), OMB Circular A-87 (Cost Principles for State, Local and Indian Tribal Governments) relocated to 2 CFR Part 225 (http://www.access.gpo.gov/nara/cfr/waisidx_10/2cfr225_10.html (http://www.access.gpo.gov/nara/cfr/waisidx_10/2cfr225_10.html)), and OMB Circular A-122 (Cost Principles for Non-Profit Organizations) relocated to 2 CFR Part 230 (http://www.access.gpo.gov/nara/cfr/waisidx_07/2cfr230_07.html (http://www.access.gpo.gov/nara/cfr/waisidx_07/2cfr230_07.html)).

Weekly TOC for this Announcement (/grants/guide/WeeklyIndex.cfm?10-03-14)
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